UNITED STATES PATENT AND TRADEMARK OFFICE

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2624	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)
Office Action Summary	10/540,444	GUITTET ET AL.
	Examiner	Art Unit
	ANTHONY MACKOWEY	2624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2009*.
2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.
    4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1-27* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☒ The drawing(s) filed on *25 June 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    a)☒ All   b)☐ Some * c)☐ None of:
      1.☐ Certified copies of the priority documents have been received.
      2.☐ Certified copies of the priority documents have been received in Application No. _____.
      3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO/SB/08)
    Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____.
5)☐ Notice of Informal Patent Application
6)☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-27 have been considered but are moot in view of the new ground(s) of rejection.

The indicated allowability of claims 2, 5, 7, 8, 9, 11, 14, 16, 17 and 18 is withdrawn.

Claim Objections

Claims 19, 21, 22, 24 and 26 objected to because of the following informalities:

Claim 19 contains a grammatical error reciting "for controlling operation of computer apparatus" in lines 2-3.

Claim 21 contains grammatical errors reciting "for controlling operation of computer apparatus" in lines 2-3 and "the instructions are for… determine…determine...and compare..." The verbs are in the wrong tense.

Claims 22, 24 and 26 contain errors similar to those above.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-18 are rejected under 35 U.S.C. 112 first <u>and</u> second paragraphs as attempting to define a product (i.e., machine or apparatus) entirely by virtue of its function, in the absence of any recited structure.

Products must distinguish over the prior art in terms of their structure (or structure + structure's function when claimed functionally) rather than function alone (MPEP 2114). Therefore, an "apparatus" not having structural limitations fails to "particularly point out and distinctly claim ..." the invention in accordance with 35 U.S.C. 112, 2nd paragraph.

The recitation of the "computer apparatus being programmed to..." does not distinctly define any structure of the computer apparatus. It only defines the functions the apparatus is capable of performing.

Furthermore, while the specification disclosure may be enabling for a plurality of structural elements performing the claimed functions [1], the specification does not reasonably provide enablement for a single structural element (or no structural elements) performing all of the claimed functions. That is, given the claim in question, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims ("A single means claim, i.e., where a means recitation does not appear in combination with another recited element of means, is subject to an undue breadth rejection under 35 U.S.C. 112, first paragraph" because a single means claim covers "every conceivable means for achieving the stated purpose" and "the specification disclosed at most only those means known to the inventor" - *MPEP, at paragraph 2164.08(a)*).

Applicant is advised to define the apparatus by virtue of the individual structural element

that serve to perform the individual functions recited in the corresponding method claim.

[1] Even when an apparatus is disclosed as being computer implemented (e.g., software

implemented on hardware), the requirement remains that there be some structure recited in the

body of the claim (e.g., a processor and a memory storing a program which when implemented

performs the method steps). For purposes of "means plus function" language, individual

disclosed steps corresponding to computer program elements operating on a processor (e.g.,

inputting, filtering, detecting and resolving) may be considered as separate means (*Dossel*, 115

F.3d at 946–47, 42 USPQ2d at 1885).

As the recited functions do not impart structural limitations on the claimed apparatus, the

examiner need not give patentable weight the recited functions as they do not define the structure

of the apparatus. If a prior art structure is capable of performing the intended use, then it would

meet the requirements of the claims. In the case of the present application, the invention is

disclosed as implemented by a conventional computer system running a program. Thus, any

computer system with suitable processing capabilities would be capable of performing the

functions of the claims if suitably programmed to do so, and therefore would meet the structural

requirements of the claims.

Claims 19-27 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the

written description requirement. The claims contains subject matter which was not described in

the specification in such a way as to reasonably convey to one skilled in the relevant art that the

inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 19, 21, 26 and 27 have been amended to recite, "[a] computer software product comprising a computer-readable hardware medium containing computer readable instructions." However, while the examiner finds support for a computer-readable hardware medium containing computer readable instructions in the originally filed disclosure (page 18, lines 21-28), the examiner is unable to find support for a **computer software product** comprising a computer-readable hardware medium containing computer-readable instructions. Dependent claims 20 and 27 have also been amended to recite "computer software product."

Claim 22 has been amended to recite, "a computer software program comprising a computer readable hardware medium containing computer readable instructions." This recitation appears to be a result of a typographical error, as computer-readable hardware mediums conventionally comprises software programs rather than vice versa, and claims 19, 21 and 26 have been amended to recite "computer program products". However, the examiner is unable to find support in the specification for a "software program comprising a computer readable hardware medium containing computer readable instructions" or a "computer software product" as previously addressed with regard to claims 19, 21, 26 and 27 herein above.

Claims 19-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As the originally filed disclosure fails to provide adequate support for a computer software product, as recited in claims 19, 20, 21, 26 and 27, it cannot be known what is meant by "computer software product" and how it should be interpreted.

Claims 23, 24 and 25 recite the limitation "a computer software product" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claims 23, 24 and 25 depend from claim 22 but claim 22 recites a "computer software program" not a "computer software product".

Further regarding claim 22, it is unclear how a computer program can comprise a computer-readable hardware medium.

Also regarding claims amended claims 19-27:

Claim 19, lines 2-3 and 6 recite, "computer readable instructions for controlling operation of computer apparatus…" and "wherein the instructions are for…"

Claim 20, line 2 recites, "wherein the instructions are also for..."

Claim 21, lines 2-3 and 5 recite, "computer readable instructions for controlling operation of computer apparatus…" and "wherein the instructions are for…"

Claim 22 recites, lines 2-3 and 6 recite, "computer readable instructions for controlling operation of computer apparatus…" and "the instructions being for…"

Claim 23, line 2 recites, "wherein the computer-readable instructions include instructions for…"

Claim 24, lines 2-5 recite, "wherein the computer readable instruction for scoring…are for providing" and "and the product also includes instructions for…"

Claim 25, lines 2-3 recite, "wherein the computer readable instructions include instructions for..."

Claim 26, lines 2-3 and 5-6 recite, "computer readable instructions for controlling operation of computer apparatus…" and "the instructions being for implementing the steps of…"

Claim 27, lines 2-4 recite, wherein the computer-readable instructions include

instructions for…"

While the above recitations are followed by functions or steps, the use of the above

language makes it unclear where a preamble of a claim ends and where the body of the claim

begins. The use of such language makes it unclear whether the recited steps are accorded

patentable weight or are recitations intended use for the "computer-readable instructions". The

claim language is questionable as to whether the instructions actually instruct a computer

apparatus to explicitly perform the recited steps/functions or are instructions instructing the

apparatus to perform other functions which enable the recited functions to be performed.

Examiner has concluded that the language of claims 19-27 is that of intended use for the

computer readable instructions. The language of the claims do not positively or actively require

the recited functions be performed but merely require that the instructions permit or enable the

recited functions to be performed.

Claim Rejections - 35 USC § 101

The text of those sections of Title 35, U.S. Code not included in this action can be found

in a prior Office action.

Claims 1-9 are rejected under 35 U.S.C. 101 as not falling within one of the four statutory

categories of invention.   Supreme Court precedent[1] and recent Federal Circuit decisions[2]

indicate that a statutory "process" under 35 U.S.C. 101 must (1) be tied to a particular machine

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[1] *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876).
[2] *In re Bilski*, 88 USPQ2d 1385 (Fed. Cir. 2008).

or apparatus, or (2) transform a particular article to a different state or thing. This is referred to as the "machine or transformation test", whereby the recitation of a particular machine or transformation of an article must impose meaningful limits on the claim's scope to impart patent-eligibility (See *Benson*, 409 U.S. at 71-72), and the involvement of the machine or transformation in the claimed process must not merely be insignificant extra-solution activity (See *Flook*, 437 U.S. at 590"). While the instant claim(s) recite a series of steps or acts to be performed, the claim(s) neither transform an article nor positively tie to a particular machine that accomplishes the claimed method steps, and therefore do not qualify as a statutory process. For example, while claim 1 recites a method comprising the steps of "obtaining the number or relatively dark image pixels by counting..." and "scoring...", no machine or apparatus is recited in the body of the claim as performing these steps, and the scope of the claim is such that these steps could be performed mentally or manually. Further, while the image pixels may be representative of Oestrogen and Progesterone Receptors expression on histological slides (physical object), the claims do not recite a transformation of data representing a physical object or substance into an external (non-data) representation of the object or substance. That is, the score is merely data or an interpretation representative of Oestrogen and Progesterone Receptors expression and it is not claimed as being externally represented (e.g. displayed).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 10-27 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,008,185 to Bacus (newly cited).

Regarding claims 10-18, Bacus discloses a computer apparatus for scoring Oestrogen and Progesterone Receptors expression (ER and PR) from image data obtained from histological slides (Figs. 1 and 2; col. 8, line 3 – col. 9, line 68) having image pixels which are dark relative to other pixels which are bright (col. 12, line 10 – col. 13, line 4). As discussed above, claimed apparatus must distinguish over the prior art in terms of their structure (or structure + structure's function when claimed functionally) rather than function alone in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, the apparatus disclosed by Bacus comprises an imaging system for capturing images of a histological slide containing samples that have been suitably stained to score Oestrogen and Progesterone expression content, and an image analysis system that is a conventional computer operating under software program control. The computer apparatus disclosed by Bacus is fully capable of performing the claimed functions if suitably programmed to do so and therefore meets the claims.

Regarding claims 19-27, Bacus discloses a computer software product comprising a computer-readable hardware medium containing computer-readable instructions for controlling

operation of a computer apparatus to implement scoring of Oestrogen and Progesterone

Receptors expression (ER and PR) from image data obtained from histological slides (Figs. 1

and 2; col. 8, line 3 – col. 9, line 68) having image pixels which are dark relative to other image

pixels which are bright (col. 12, line 10 – col. 13, line 4). As discussed above, the claim language

is such that the recited functions are a recitation of intended use for the claimed computer

software product. Bacus discloses an image analysis application for scoring Oestrogen and

Progesterone Receptor expression that is implemented by a conventional computer system

comprising a disk drive and reading an application program from a disk in the disk drive and

loading the application program to control the various hardware elements of the apparatus (col.

9, lines 5-16). While the functions of apparatus, in accordance with the instructions, disclosed by

Bacus, are not necessarily the same as those recited in claims 19-27, the computer program

product comprising a computer readable hardware medium containing computer readable

instructions disclosed by Bacus provides sufficient functionality to the computer that would

enable the claimed functions to be performed. Therefore, the computer program product

disclosed by Bacus meets the requirements of the claims.

Claims 1, 2, 10, 11, 19 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by

US 6,697,509 to De La Torre-Bueno (previously cited).

Regarding claim 1, De La Torre-Bueno discloses a method of scoring Oestrogen and

Progesterone Receptors expression (ER and PR) from image data obtained from histological

slides having image pixels which are dark relative to other image pixels which are bright (col. 1,

lines 6-54; col. 2, line 24 – col. 4, line 46), the method comprising:

obtaining the number of relatively dark pixels having intensities below a predetermined

intensity threshold (col. 3, line 4 – col. 4, line 13, *pixel counter for unmasked pixels*), and

scoring ER or PR in accordance with the magnitude of the number so obtained (col. 4,

lines 14-34, *mean DAB is accumulated result divided by number of pixels*).

Regarding claims 10 and 19 De La Torre-Bueno further discloses a computer apparatus

programmed to perform the method (Fig. 1; col. 4, lines 47-55) and a computer software product

comprising a computer-readable hardware medium containing computer-readable instructions for

controlling the computer apparatus to perform the method (col. 4, lines 47-55).

Regarding claim 2, 11 and 20, De La Torre-Bueno discloses a method of scoring

Oestrogen and Progesterone Receptors expression (ER and PR) from image data obtained from

histological slides having image pixels which are dark relative to other image pixels which are

bright (col. 1, lines 6-54; col. 2, line 24 – col. 4, line 46), the method comprising:

determining the number of relatively dark pixels by transforming the image data to a

different image space having an intensity image plane and counting the number of pixels having

intensities below a predetermined intensity threshold (col. 2, lines 27-44; col. 3, line 4 – col. 4,

line 13, *A/D transform; HSI transform; pixel counter for unmasked pixels*), and

scoring ER or PR in accordance with the magnitude of the number so obtained (col. 4,

lines 14-34, *mean DAB is accumulated result divided by number of pixels*).

Further regarding claims 11 and 20 De La Torre-Bueno further discloses a computer

apparatus programmed to perform the method (Fig. 1; col. 4, lines 47-55) and a computer

software product comprising a computer-readable hardware medium containing computer-

readable instructions for controlling the computer apparatus to perform the method (col. 4, lines

47-55).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in
> section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are
> such that the subject matter as a whole would have been obvious at the time the invention was made to a person
> having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the
> manner in which the invention was made.

Claims 4, 5, 13, 14, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable

over Bacus in view of "Computer-Aided Detection of Breast Cancer Nuclei" to Schnorrenberg et

al. (previously cited in Applicant's IDS, hereafter referred to as "Schnorrenberg").

Regarding claims 4, 13 and 22, Bacus discloses a method of scoring Oestrogen and

Progesterone Receptors expression (ER and PR) from image data obtained from histological

slides, the image data comprising pixels corresponding to blobs and pixels corresponding to the

background (Figs. 2 and 10; col. 3, line 60- col. 5, line 26; col. 12, line 10 – col. 15, line 59), and

the method having the steps of:

determining what proportion of total blob area is brown blob area in an image (col. 5,

lines 33-55; col. 13, lines 11-16; col. 14, lines 54-62) and

scoring ER or PR in accordance with the brown blob area proportion (col. 5, lines 33-55;

col. 13, lines 11-16; col. 14, lines 54-62).

Bacus discloses a generating a QIC score using computerized image analysis and

describes visual semi-quantitative analysis and determining an HSCORE. While Bacus discloses

scoring in accordance with the brown blob area proportion, Bacus is silent with regard to

determining brown blob area proportion thresholds to quantify scoring, and is therefore silent

with regard to comparing the brown blob area proportion with the brown blob area proportion

thresholds and scoring ER or PR in accordance therewith. Schnorrenberg discloses a computer

aided detection system of breast cancer nuclei in which scoring is based on the proportion of

positive nuclei. Schnorrenberg discloses an HSCORE technique wherein proportion thresholds

are determined to quantify scoring and observed proportion values are compared to the

proportion thresholds, and scoring ER or PR in accordance therewith (page 137, Fig. 8; pages

138-139, Appendix A, Table IV).

It would have been obvious to one of ordinary skill in the art at the time the invention

was made to combine the teachings of Bacus and Schnorrenberg such that the method disclosed

by Bacus could be modified to include determining brown blob area proportion thresholds to

quantify scoring, and comparing the brown blob area proportion with the brown blob area

proportion thresholds and scoring ER or PR in accordance therewith, analogously to the

HSCORE disclosed by Schnorrenberg. The Supreme Court has held that in analyzing the

obviousness of combining elements, a court need not find specific teachings, but rather may

consider "the background knowledge possessed by a person having ordinary skill in the art" and

"the inferences and creative steps that a person of ordinary skill in the art would employ." See

KSR Int'l v. Teleflex Inc., 127 S. Ct. 1727, 1740-41, 82 USPQ2d 1385, 1396 (2007). To be

nonobvious, an improvement must be "more than predictable use of prior art elements according

to their established functions." *Id.* Here the combination is the predictable use the brown blob

proportion as disclosed by Bacus, the concept of quantifying the percentage of nuclei disclosed

by Schnorrenberg, and scoring ER or PR as disclosed by both Bacus and Schnorrenberg. The

combination would predictably result in determining the brown blob area proportion as disclosed

by Bacus, but rather than multiplying the percentage and intensity directly, as disclosed by

Bacus, the proportion and intensity are represented as quantified numbers as disclosed by

Schnorrenberg, and scoring ER and PR accordingly.

As discussed herein above, Bacus further discloses a computer apparatus programmed to

perform the method of the invention and a computer software product [program] comprising a

computer-readable hardware medium containing computer-readable instructions for

implementing the method (Figs. 1 and 2; col. 8, line 3 – col. 9, line 68). Thus, the combination of

Bacus and Schnorrenberg discloses or suggests all the limitations of claims 13 and 22 regardless

of patentable weight, and arguments analogous to those presented above for claim 4 are

applicable to claims 13 and 22.

Regarding claims 5, 14 and 23, Bacus discloses a method of scoring Oestrogen and

Progesterone Receptors expression (ER and PR) from image data obtained from histological

slides, (Figs. 2 and 10; col. 3, line 60- col. 5, line 26; col. 12, line 10 – col. 15, line 59), the

method including the steps of:

remapping pixel intensities in the image data to increase the contrast of relatively darker image regions and to transform relatively brighter image regions into a contrast free background (col. 10, lines 51-64; col. 12, lines 10-63; col. 13, line 30 - col. 14, lines 41),

converting the remapped image data into image data corresponding to thresholded binary images form which total blob area and brown blob area are discernible respectively (col. 10, lines 51-64; col. 12, lines 10-63; col. 13, line 30 - col. 14, lines 41),

expressing brown blob area as a proportion of total blob area (col. 5, lines 33-55; col. 13, lines 11-16; col. 14, lines 54-62), and

scoring ER or PR in accordance with the brown blob area proportion (col. 5, lines 33-55; col. 13, lines 11-16; col. 14, lines 54-62).

Regarding determining brown blob area proportion thresholds to quantify scoring, and comparing the brown blob area proportion with the brown blob area proportion thresholds and scoring ER or PR in accordance therewith, arguments analogous to those presented above for claims 4, 13 and 22.

As discussed herein above, Bacus further discloses a computer apparatus programmed to perform the method of the invention and a computer software product [program] comprising a computer-readable hardware medium containing computer-readable instructions for implementing the method (Figs. 1 and 2; col. 8, line 3 – col. 9, line 68). Thus, the combination of Bacus and Schnorrenberg discloses or suggests all the limitations of claims 14 and 23 regardless of patentable weight, and arguments analogous to those presented above for claim 5 are applicable to claims 14 and 23.

Claims 6, 15, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Bacus and Schnorrenberg as applied to claims 4, 13 and 22 above, and further in view of De La

Torre-Bueno.

As to claims 6, 15 and 24, while the combination of Bacus and Schnorrenberg, as applied

above, further discloses comparing the brown blob area proportion with the brown blob area

proportion thresholds provides a first contribution to an ER and PR score, providing a second

contribution to the ER or PR score based on intensity, and combining the first and second

contributions (Bacus, col. 15, lines 34-59 and col. 17, lines 14-33; Schnorrenberg, pages 137,

Fig. 8; pages 138-139, Appendix A, Table IV), they do not explicitly disclose providing the

second contribution by determining the number of pixels in an image having intensities below a

predetermined intensity threshold and which are thereby relatively dark compared to other pixels

in the image and deriving the second contribution in accordance with the magnitude of the

number of relatively dark pixels. However, as identified above with regard to claims 1, 2, 10, 11,

19 and 20, De La Torre-Bueno discloses ER scoring by determining the number of pixels in an

image having intensities below a predetermined intensity threshold and which are thereby

relatively dark compared to other pixels in the image and deriving a score in accordance with the

magnitude of the number of relatively dark pixels (col. 1, lines 6-54; col. 2, line 24 – col. 4, line

46) Further De La Torre-Bueno discloses converting the DAB intensity to a traditional 0-3 scale

(col. 4, lines 14-19) which is similar to the staining intensity scale disclosed by Schnorrenberg

(Table IV).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Bacus, Schnorrenberg and De La Torre-Bueno such that the second contribution to the ER or PR score (Staining Intensity) disclosed or suggested by the combination of Bacus and Schnorrenberg could be provided by determining the number of pixels in an image having intensities below a predetermined intensity threshold and which are thereby relatively dark compared to other pixels in the image and deriving a score in accordance with the magnitude of the number of relatively dark pixels, as disclosed by De La Torre Bueno, in order to provide more accurate and precise scores (De La Torre Bueno, col. 1, lines 31-42; col. 1, line 66 - col. 2, lines 6).

Regarding claim 25, the combination of Bacus, Schnorrenberg and De La Torre-Bueno, as applied to claims 22 and 24 above, further discloses determining the number of relatively dark image pixels by transforming the image data to a different image space having an intensity plane and counting the number of pixels having intensity below a predetermined intensity threshold (De La Torre-Bueno, col. 2, lines 27-44; col. 3, line 4 – col. 4, line 13).

Claims 7, 8, 16, 17 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Bacus, Schnorrenberg and De La Torre-Bueno.

Claims 7, 8, 16, 17 and 26 are drawn to various combinations of elements previously addressed in the rejections of claims 4, 5, 6, 13, 14, 15, 22, 23, 24 and 25. Therefore, arguments analogous to those presented for claims 4, 5, 6, 13, 14, 15, 22, 23, 24 and 25 above are applicable to claims 7, 8, 16, 17 and 26.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANTHONY MACKOWEY whose telephone number is (571)272-7425. The examiner can normally be reached on M-F 9:00-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Matthew Bella can be reached on (571) 272-7778. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Matthew C Bella/
Supervisory Patent Examiner, Art Unit
2624

AM
3/15/09